MAR 2 8 2012

K112774

510k SUMMARY BD Recykleen™ Sharps Collector

Date: March 28, 2012

1. **Submitted By**

BD Medical Surgical Systems
Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, New Jersey, 07417 USA

2. **Contact Information**

Primary Contact
Eileen Hiller
Director, Regulatory Affairs
BD Medical Surgical Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417 USA
201-847-4570
Eileen_Hiller@BD.com

Secondary Contact
Sergio Gadaleta
Vice President, Regulatory Affairs
BD Medical Surgical Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417 USA
201-847-4496
Sergio_Gadaleta@BD.com

3. **Device identification:**

Trade Name:	BD Recykleen™ Sharps Container
Common Name:	Sharps Container
Classification:	MMK - Accessory to hypodermic single lumen needles
CFR Reference:	21CFR 880.5570 – Class II
Classification Panel:	General Hospital

4. **Predicate devices:**

Substantial equivalence is being claimed to the following legally marketed devices:

Trade Name:	BD Guardian™ Sharps Collector
Common Name:	Sharps Container
Classification:	MMK - Accessory to hypodermic single lumen needles
Predicate 510k No	K943134 Cleared 11/07/1994
CFR Reference:	21CFR 880.5570 – Class II

Classification Panel: General Hospital

5. Product Description:

The BD Recykleen™ Sharps Collector is a single use device designed for the safe disposal of regulated medical waste such as contaminated sharps waste. All materials, including sides, bottom, and top are manufactured with polypropylene or polyolefin plastics, the same type of material used in current BD Sharps Collectors and BD Recykleen™ Sharps Collectors. The predicated devices were previously cleared under K943134.

The basis of this new Traditional 510(k) submission is for a material change of the sharps collector. The material change, which will incorporate the use of a new resin grade of recycled plastic recovered from the hospital and healthcare facility medical sharps waste-stream. The use of post-hospital recycled resins in the manufacture of the BD Recykleen Sharps Collectors has been demonstrated to be safe and effective. BD has developed the BD ecoFinity™ Life Cycle Solution, which is a program for recycling clinically used hospital-generated medical sharps waste. The basics of this new recycling program are that plastics, recovered from recycling post-hopital sharps waste, are utilized to manufacture new sharps collectors rather than being treated and disposed in landfills or incinerated. After sanitization, the treated sharps waste is separated into metal, light plastics, and other materials. The light plastics are recovered, extruded and pellitized into a final resin pellet form. The recycled resin pellets are then injection molded into components that make up the finished BD Recykleen™ Sharps Collectors.

The technological and performance characterisitics of the BD Recykleen™ Sharps Collectors (new device) is similar to BD Guardian Sharps Collectors (predicate device). There is no change to the intended use of the new or predicate Sharps Collectors, the collector design and technological and performance characteristics remain unchanged.

BD Sharps Collectors may be used with optional accessories, stabilizer and brackets, that provide the customer choices for further security and enhanced stability during usage. The 8Qt and 6 Gallon Product Instructions for Use list the compatible brackets and stabilizer accessories available.

Brackets are designed to secure the collector to a wall or cart. Some bracket accessories include additional security via a locking mechanism.

Stabilizers: Stabilizers are designed to stabilize collectors on a countertop or other flat surface.

6. **Intended Use:**

The BD Recykleen™ Sharps Collectors intended use:

Sharps Collectors are intended to be used for disposal of contaminated medical sharps in health care facilities

7. **Comparison to Predicate Devices:**
The sharps container is similar to the predicated in intended use, materials, measuring principle and performance.

FEATURE	MODIFIED DEVICE BD RECYKLEEN™ SHARPS COLLECTOR	PREDICATE DEVICE BD GUARDIAN™ SHARPS COLLECTOR
Closable	Same	Yes, Snap fit cap/closure
Puncture Resistant	Same ASTM F2132-01 (2008), "Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps".	Yes Passes proposed ASTM F04.65.01 procedure (Current draft in 1994)
Leakproof on sides and Bottom	Same	Yes
Labeled or Color-Coded:	Same	Sharps/Infectious Waste Yes
Biohazard Warning Label		
Fluorescent orange or orange-red with lettering in contrasting color	Same	Yes
Affixed to container	Same	Yes
Red Container or label	Same	Yes
Recycled Content Label	Patient Room Collectors Recycled Content- Minimum 20% Nestable Collectors Minimum 50% Recycled Content	NA

FEATURE	MODIFIED DEVICE BD RECYKLEEN™ SHARPS COLLECTOR	PREDICATE DEVICE BD GUARDIAN™ SHARPS COLLECTOR
Capable of maintaining stable, upright position.	Same	Yes
No feature to bend, break, or shear needle.	Same	No feature present.
Unwinder	Same	Unwinder is designed for one-handed operation on containers.
Reusable Sharp Container	Same	Labeling is "Single Use Only".
Overfill Indication	Same	"Do Not Overfill" or "Fill to this Level Only" is labeled or embossed on container at the location of overfill. Labeling includes a "Fill Line."
Locking Enclosure	Same	All models have the option for use of security locks and keys
Holder to secure to walls	Same	Product is capable of attaching to wall-mount or cart-mount.
Materials	Polyolefinic resins: Virgin polypropylene Post consumer Post industrial Post hospital	Polyolefinic resins- Virgin Polypropylene
Construction	Same	Injection molded Container, Injection molded Lids/Closures
Clarity	Same	Each Collector has a minimum of one translucent component, either base or top. Some models with clear "see thru" tops.
Recycled Content	Nestable Sharps Collectors minimum 50%	N/A

The Device Models Subject to this submission are listed below. The BD Recykleen™ Sharps collector's dimensions, access openings, features and capacity are essentially equivalent to the predicate devices.

Family	BD Recykleen™Sharps Collector	Access Opening and Closure	Access Opening Size	Length (in)	Width (in)	Height (in)	Weight (grams)	Capacity
Nestable Sharps Collectors	8 Quart Model No. 305059	Funnel Top, with restricted access petals Hinge Cap	1.5 "x 1.125" with flexible petals	9.75	10.00	6.75	446	8 Quarts
	6 Gallon Model No. 305160	Open top with restricted access opening Hinge Cap	2.5" diameter	17.50	12.50	8.50	935	6 Gallons

8. Discussion of Similarities and Differences in New and Predicate Product

Intended Use Comparison

The indications for use of the new BD Recykleen™ Sharps Collector are not new indications in that they are the same as those for the predicated devices. Sharps collectors and other predicated devices are containers intended for the disposal of contaminated medical waste within healthcare facilities.

Design and Materials Comparison

The design and functionality of the sharps collectors and predicated devices are identical. They are constructed from polypropylene and contain a component(s) made from recycled polyolefin plastics and are intended for single use only. All of the devices conform to recognized standard, ASTM F-2132-01 for needle penetration resistance. They have features to prevent contact between user and the contents, and are designed for easy and safe determination of fullness. None of the devices have features that bend, break, or shear needles.

9. Summary of Performance Bench Testing of Device Modifications

9.1 Performance Standards:

No performance standards have been established under Section 514 for this product code. All recognized standards and other regulations and guidance documents that were used in this 510(k) have been listed in Section 20.

The performance testing demonstrates compliance with the recognized consensus standard, ASTM F 2132-01 (Reapproved 2008) e1, "Standard Specification for Puncture Resistance of Materials Used in Collectors for Discarded Medical Needles and Other Sharps." In addition the relevant FDA guidance document, "Guidance on the Content and Format of Premarket Notification [510(K)] Submission for Sharps Collectors" dated October 1993, was used to identify applicable physical and mechanical features of the modified and predicate devices.

All applicable standards have been used to show that the BD Recykleen Container family is substantially equivalent to the appropriately listed predicate devices.

The performance testing summary demonstrates substantial equivalence between the modified device and the predicate devices. The new sharps collectors have been tested by appropriate methods with respect to relevant FDA guidance documents, FDA recognized ASTM standards F 2132-01 and OSHA regulations 29 CFR Part 1910:1030. No new issues of safety and effectiveness were raised with the testing performed, and the BD Recykleen Containers are considered substantially equivalent to its predicate device.

9.2 Performance Testing (Bench) -Product Testing

The BD Recykleen™ Sharps Containers incorporate the identical collector design features, performance characteristics, manufacturing technology. The results of product performance testing demonstrated equivalent performance to predicate device performance and no new issues of concern were raised.

Impact Resistance

Impact resistance was assessed such that no open fractures or disassembly results when a filled collector is dropped. The container is filled with assorted sharps or syringes with or without needles, or equivalent weight using resin beads and sealed as if ready for transport. The collector is dropped 39" from the base onto a hard surface floor.

Pass/Fail Criteria: No gross fractures (external wall of container is open enough to allow escape of solid contents) or loss of contents are permitted. Stress fractures (crack in external wall where wall does not separate to release solid contents) are permitted.

Needle Penetration Resistance

Needle Penetration Resistance is based on ASTM F2132-01, "Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps", for minimum and average needle penetration force. The test method involves cutting 12 samples from needle containment areas of the sharps collector. Each sample is tested using a motorized mechanical tester (Instron, ATS or equivalent) with a new 21 gauge x 1" needle, each penetration is tested at 4"/minute.
Pass/Fail Criteria: No one needle puncture force can be less than 2.8 lbf and average puncture force of 3.4 lbf must be met to be acceptable.

Leak Resistance

The Leak Resistance testing is based on OSHA Specification (29 CFR 1910.1030) - The container is filled with water to the labeled fill line and left to stand on its base 1 hour.

Pass/Fail Criteria: No leaks are observed with product standing in upright position.

Transit Damage Resistance:

Transit Damage testing demonstrates the product is free from any visible damage that may affect customer usage, safety, or satisfaction when products are packaged in shipping cases and dropped. The appropriate number of products are packaged in the appropriate shipping case and sealed as if ready for shipment. The shipping case is dropped from 24" onto a hard surface floor in 10 different orientations.

Pass/Fail Criteria: The product is free from any visible damage that may affect customer usage, safety, or satisfaction when products are packaged in the shipping case and dropped with a 90% pass rate.

Performance Testing- Needle Penetration Resistance- Comparison of all Recycled Resin Grades and blend of resins in use

The critical performance characteristic for Sharps Collectors is Needle Penetration Resistance (NPR). Individual NPR regression analyses of wall thickness versus needle puncture force were completed for each of the following: 100% recycled resin grades (PH, PI, and PC); virgin and recycled resin blends. The NPR regression curves were completed for each virgin material, recycled resin and resin blend formulation. Each resin material is characterized to have a unique minimum wall thickness to meet ASTM F 2132-01.

9.3 Safety Tests

To demonstrate that post hospital recycled resins are substantially equivalent to the PC and PI recycled resins and virgin resins used in the predicate Sharps Collectors, additional safety tests were conducted. These tests were selected to eliminate

potential concerns of residual resin contamination after completion of the sanitization, separation, recycling and extrusion processes.

Pellet samples or test plaques representing 100% PH, 100% PI, and 100% PC recycled and virgin resins were tested according to those listed in Table 6.

All Safety Tests demonstrated equivalent performance between the principle and predicate Sharps Collectors and individual resins tests.

Table 6
Summary of Safety Tests

Safety Test	Standards/Method	Principle Device	Predicate Device
Biocompatibility Testing • Cell Toxicity	ISO 10993	passed	passed
• Murine Local Lymph Node Assay	ISO 10993	passed	passed
• Primary Dermal Irritation	ISO 10993	passed	passed
Bioburden- All test samples- non sterile Samples Resin • Pellets Sharps Collectors • Interior • exterior	ISO 11737-1	(PI,PC,PH) <46 CFU/10g 1.5 CFU/2 swabs 10.8 CFU/100ml	Virgin PP < 4.8 CFU/10g 3.7 CFU/2 swabs 3.1 CFU/100mL
Chemical Analysis Extractible: liquid extracts (water/alcohol) Leachable: volatiles/headspace	LC/DAD/MS GC/MS	Same No significant differences	Same No significant differences
Heavy Metals	ICP/MS XRF	Passed TPCH <100ppm	Passed TCPH <100ppm

Conclusion:
BD Recykleen™ Sharps Collectors proves to be substantially equivalent to the respective predicate sharps collectors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Eileen Hiller
Manager of Regulatory Affairs
Becton, Dickinson and Company
BD Medical Surgical
1 Becton Drive MC 237
Franklin Lakes, New Jersey 07417

MAR 2 8 2012

Re: K112774
Trade/Device Name: BD Recykleen™ Nestable Sharps Collectors
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: March 20, 2012
Received: March 22, 2012

Dear Ms. Hiller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112774

Device Name: BD Recykleen™ Nestable Sharps Collectors

Model Number	**305059**
Size	**8 Quart Nestable Sharps Collector**
Model Number	**305160**
Size	**6 Gallon Nestable Sharps Collector**

Indications for Use: **Sharps collectors are intended to be used for the disposal of contaminated medical sharps in health care facilities.**

Prescription Use _____
(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Claverie-Wills

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112774

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